CTC/ WRAIR
503 Robert Grant Avenue, Room 2W78
Silver Spring, Maryland 20910
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www.wrairclinicaltrials.com

WRAIR study #1736, Principal Investigator Dr. Guerrero

We are conducting a study of an investigational vaccine for plague at the Walter Reed Army Institute of Research Clinical Trials Center. The purpose of this research study is to examine the safety of two schedules of investigational vaccine administration. The study will also examine the antibody response between the two dosage schedules. Antibodies are proteins produced in the body after exposure to vaccines or foreign substances from infections and are part of the body's immune defenses against future exposure to the same infection. The study will also examine if the addition of aluminum hydroxide in the vaccine will strengthen the immune response.

It is impossible to get the disease called "plague" from the vaccine because the vaccine does not contain plague bacteria.

This study is 18 months long. Participants will receive three vaccinations at two different schedules. For seven days after each of the 3 injections participants will be required to complete an electronic diary. The study staff will demonstrate how to use this electronic diary and participants will be required to answer questions each day for seven days about how they are feeling, their oral temperature, and how the vaccination site looks. Participants will complete the diary by calling a toll-free telephone number daily for 7 days after each vaccination to report any adverse reactions to the vaccination. Depending on which schedule is assigned, there will be a total of 15 or 16 office visits and blood draws, and approximately 4 follow-up phone calls. If you are a female you cannot get pregnant within 28 days after the third injection. You should not become pregnant during the entire study period which is 16-18 months plus the 28 days after the last injection.

At the briefing you will be provided information about the study and given an opportunity to ask questions. If you decide after hearing about the study that you would like to screen for the study you will read and sign an informed consent document. You will then take a short quiz to make sure you have correctly understood the information. You will need to fast for 8 hours prior to the first visit, that is have nothing to eat or drink except water, for your blood tests. We will test for HIV, hepatitis, routine chemistry and complete blood count. We will also review your medical history, perform a study-related physical exam and take your vital signs. We will collect information on any medications you are taking, collect urine for a urinalysis and drug screen, perform an EKG, and females will have a pregnancy test.

All study-related procedures and study vaccinations are performed at no cost. Participants will be compensated for their time. Compensation will be between $1500 and $1650.

Brief Overview of Inclusion Criteria - You must be:
Healthy adult, 18 to 55 years of age
Willing to have blood samples stored for future plague research

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Brief Overview of Exclusion Criteria - You are not eligible to participate if you:
Weigh less than 110 pounds (BMI less than 18 or greater than 35)
Active duty military
Female breastfeeding or planning to become pregnant
Previously vaccinated or exposed to any form of plague
Allergy to vaccines which contain aluminum
History of nerve, heart, lung, liver or kidney disease
Positive for HIV or hepatitis C
Problems with drug or alcohol abuse
Have multiple sclerosis, lupus or rheumatoid arthritis
Are taking steroid medications
Currently receiving an investigational product
Unable to complete visits over an 18-month period

Would you like to come in for a full study briefing with a screening to follow if you decide you would like to participate?